

Serial No.: 09/091,062
Group Art Unit: 1616

BEST AVAILABLE COPY

RECEIVED
CENTRAL MAIL CENTER

JAN 24 2005

Amendments to the Claims:

1. (Currently Amended) A dosage unit comprising a mucosal surface-coat-forming film, wherein the mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of ~~an erectile dysfunction active agent~~ sildenafil citrate and a mucosal adhesion enhancer, wherein the mucosal adhesion enhancer is a starch graft copolymer.
2. (Original) The dosage unit of claim 1, wherein the mucosal adhesion enhancer is a copolymer of starch and acrylic acid.
3. (Original) The dosage unit of claim 1, wherein the film exhibits a dry tack value of less than 3.5g.
4. (Original) The dosage unit of claim 1, wherein the film exhibits a dry tack value of less than 2.0g.
5. (Original) The dosage unit of claim 1, wherein the film exhibits a wet tack value of greater than 35g.
6. (Original) The dosage unit of claim 1, wherein the water-soluble hydrocolloid exhibits a gelation temperature that is greater than 70°C for a 2% polymer solution.
7. (Previously Presented) The dosage unit of claim 1, wherein the water-soluble hydrocolloid exhibits a hydration rate in 24 hours of 5-20% increase in the weight percent of the water-soluble hydrocolloid at 75% humidity at room temperature.
8. (Original) The dosage unit of claim 1, wherein the water-soluble hydrocolloid is a polymer selected from the group consisting of a natural, semi-natural and synthetic biopolymer.

BEST AVAILABLE COPY

Serial No.: 09/091,062

Group Art Unit: 1616

9. (Previously Presented) The dosage unit of claim 8, wherein the water-soluble hydrocolloid is selected from the group consisting of a polysaccharide and a polypeptide.

10. (Original) The dosage unit of claim 8, wherein the water-soluble hydrocolloid comprises a hydroxypropylmethylcellulose polymer.

11. (Original) The dosage unit of claim 10, wherein the hydroxypropylmethylcellulose polymer has a molecular weight of less than 200,000 Daltons.

12. (Original) The dosage unit of claim 1, wherein the film further comprises at least one of an emulsifier, a plasticizer, a taste modifying agent, a water soluble inert filler, a preservative, a coloring agent, a stabilizer and a buffering agent.

13. (Original) The dosage unit of claim 1, wherein the film further comprises an emulsifier present at a concentration in the range of 0.1 to 10 wt% of the dosage unit.

14. (Original) The dosage unit of claim 1, wherein the film further comprises a taste modifying agent comprising at least one of a sweetening agent, a flavoring agent and a taste masking agent.

15. (Original) The dosage unit of claim 1, wherein the film further comprises a water soluble inert filler present at a concentration in the range of 0.5 to 50 wt% of the dosage unit.

16. (Original) The dosage unit of claim 1, wherein the film further comprises a preservative present at a concentration in the range of 0.01 to 10 wt% of the dosage unit.

17. (Original) The dosage unit of claim 1, wherein the active agent is present at a concentration in the range of 0.01 to 75 wt% of the dosage unit.

BEST AVAILABLE COPY

Serial No.: 09/091,062
Group Art Unit: 1616

18. (Canceled)
19. (Canceled)
20. (Original) The dosage unit of claim 1, wherein the film has a dry film thickness in the range of 1 to 20 mil.
21. (Original) The dosage unit of claim 20, wherein the film has a dry film thickness of less than 10 mils.
22. (Original) The dosage unit of claim 1, wherein the film exhibits a tensile strength greater than 1500 psi.
23. (Original) The dosage unit of claim 1, wherein the film exhibits a % elongation of less than 20%.
24. (Canceled)
25. (Original) The dosage unit of claim 1, wherein the film exhibits a dissolution time in the range of 1 to 300 seconds upon application to an oral mucosal surface.
26. (Currently Amended) The dosage unit of claim ~~52~~ 1, wherein the film exhibits a tensile strength greater than 1,500 psi, a % elongation of less than 20% and a disintegration time in the range from 1 to 300 seconds upon application to an oral mucosal surface.
27. (Currently Amended) The dosage unit of claim 1, wherein the ~~active agent~~ sildenafil citrate is encapsulated within a polymer, wherein the polymer exhibits dissolution properties that are different from those of the hydrocolloid.

Serial No.: 09/091,062
Group Art Unit: 1616

BEST AVAILABLE COPY

28. (Currently Amended) The dosage unit of claim 1, wherein the dosage unit further comprises an additional active agent ~~other than the erectile dysfunction active agent~~ sildenafil citrate.

29. (Previously Presented) The dosage unit of claim 1, wherein the mucosal adhesion enhancer is present at a concentration of up to 50% by weight.

30. (Currently Amended) A dosage unit comprising a mucosal surface-coat-forming film, wherein the mucosal surface-coat-forming film comprises a water-soluble hydrocolloid, an effective dose of ~~an erectile dysfunction active agent~~ sildenafil citrate and a mucosal adhesion enhancer; wherein the active agent is encapsulated within a polymer which exhibits dissolution properties that are different from those of the hydrocolloid; wherein the mucosal adhesion enhancer is a starch graft copolymer; wherein the film exhibits a dry tack value of less than 3.5g, a wet tack of greater than 35g, a gelation temperature that is greater than 70°C for a 2% polymer solution, a dry film thickness of not more than 20 mil, a water content of 0.5 to 10%, a tensile strength greater than 1500 psi, a modulus in the range of 35,000 to 300,000 psi, a % elongation of less than 20%, a tear propagation resistance of 0.001 to 1 N, and a dissolution time of not more than 600 seconds upon application to an oral mucosal surface.

31. (Original) The dosage unit of claim 30, wherein the mucosal adhesion enhancer is a copolymer of starch and acrylic acid.

32. (Original) The dosage unit of claim 30, wherein the film exhibits a dry tack value of less than 2.0g.

33. (Previously Presented) The dosage unit of claim 30, wherein the water-soluble hydrocolloid exhibits a hydration rate in 24 hours of 5-20% increase in the weight percent of the water-soluble hydrocolloid at 75% humidity at room temperature.

BEST AVAILABLE COPY

Serial No.: 09/091,062
Group Art Unit: 1616

34. (Original) The dosage unit of claim 30, wherein the water-soluble hydrocolloid is a polymer selected from the group consisting of a natural, semi-natural and synthetic biopolymer.

35. (Previously Presented) The dosage unit of claim 34, wherein the water-soluble hydrocolloid is selected from the group consisting of a polysaccharide and a polypeptide.

36. (Original) The dosage unit of claim 34, wherein the water-soluble hydrocolloid comprises a hydroxypropylmethylcellulose polymer.

37. (Original) The dosage unit of claim 36, wherein the hydroxypropylmethylcellulose polymer has a molecular weight of less than 200,000 Daltons.

38. (Original) The dosage unit of claim 30, wherein the film further comprises at least one of an emulsifier, a plasticizer, a taste modifying agent, a water soluble inert filler, a preservative, a coloring agent, a stabilizer and a buffering agent.

39. (Original) The dosage unit of claim 30, wherein the film further comprises an emulsifier present at a concentration in the range of 0.1 to 10 wt% of the dosage unit.

40. (Original) The dosage unit of claim 30, wherein the film further comprises a taste modifying agent comprising at least one of a sweetening agent, a flavoring agent and a taste masking agent.

41. (Original) The dosage unit of claim 30, wherein the film further comprises a water soluble inert filler present at a concentration in the range of 0.5 to 50 wt% of the dosage unit.

42. (Original) The dosage unit of claim 30, wherein the film further comprises a preservative present at a concentration in the range of 0.01 to 10 wt% of the dosage unit.

Serial No.: 09/091,062
Group Art Unit: 1616

BEST AVAILABLE COPY

43. (Original) The dosage unit of claim 30, wherein the active agent is present at a concentration in the range of 0.01 to 75 wt% of the dosage unit.

44. (Canceled)

45. (Original) The dosage unit of claim 30, wherein the film has a dry film thickness in the range of 1 to 20 mil.

46. (Original) The dosage unit of claim 45, wherein the film has a dry film thickness of less than 10 mils.

47. (Original) The dosage unit of claim 30, wherein the film exhibits a dissolution time in the range of 10 to 600 seconds upon application to an oral mucosal surface.

48. (Previously Presented) The dosage unit of claim 30, wherein the film further exhibits a disintegration time in the range of 1 to 300 seconds upon application to an oral mucosal surface.

49. (Cancelled).

50. (Currently Amended) The dosage unit of claim 30, wherein the dosage unit further comprises an additional active agent other than the ~~erectile dysfunction active agent~~ sildenafil citrate.

51. (Previously Presented) The dosage unit of claim 30, wherein the mucosal adhesion enhancer is present at a concentration of up to 50% by weight.

52. (Previously Presented) The dosage unit of claim 1, wherein the film exhibits a modulus in the range of 35,000 to 300,000 psi.

Serial No.: 09/091,062
Group Art Unit: 1616

BEST AVAILABLE COPY

53. (Previously Presented) The dosage unit of claim 1, wherein the film exhibits a dissolution time in the range of 10 to 600 seconds upon application to an oral mucosal surface.